Thermo Fisher Scientific
Clinical Diagnostics | Niche Products
46500 Kato Road | Fremont, CA 94538 USA
Tel: 510 979 5000
www.thermofisher.com

August 18, 2026

URGENT- FIELD SAFETY NOTICE
(FSCA 01-26-M)
ACTION REQUIRED

Thermo Fisher Scientific MAS® Omni•IMMUNE™ PRO
Liquid Assayed Integrated Immunoassay Control

Dear Valued Customer,
The purpose of this letter is to advise you that Microgenics Corporation, part of Thermo Fisher Scientific Inc., is conducting a Field Safety Corrective Action for the in-vitro diagnostic product listed below (Table 1). Our records indicate that you have purchased units of the affected product. Please read the following information carefully.

Table 1: Product List

Product Description	Catalog Number	Lot Number	Expiration Date (YYYY-MM-DD)	UDI
MAS® Omni•IMMUNE™ PRO Liquid Assayed Integrated Immunoassay Control, Level 1	OPRO-101	OPRO29061A	2029-06-30	00884883005327
MAS® Omni•IMMUNE™ PRO Liquid Assayed Integrated Immunoassay Control, Sample Pack	OPRO-SP	OPRO2906SA	2029-06-30	00884883005358

INTENDED PURPOSE

Thermo Scientific MAS® Omni•IMMUNE™ PRO is intended for use as an assayed control for monitoring assay conditions in many clinical laboratory determinations. Include Omni•IMMUNE PRO with patient serum specimens when assaying for any of the listed constituents. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.

REASON FOR FIELD ACTION AND DESCRIPTION OF THE ISSUE

Microgenics Corporation is initiating FSCA for the product **MAS® Omni•IMMUNE™ PRO Liquid Assayed Integrated Immunoassay Control** because we have received complaints from customers reporting vial-to-vial variability resulting in low Parathyroid Hormone (PTH) recovery for MAS® Omni•IMMUNE™ PRO Level 1, Lot OPRO29061A. No other analytes are reported to be showing variability between vials. This observed issue applies to customers who purchased the product listed in Table 1. This issue could result in a delay in reporting patient results.

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RISK TO HEALTH / IMPACT ON PATIENT RESULTS

Health hazard assessment performed by a medical officer determined that if there is a delay in reporting of patient results, there is a remote probability of Medically Reversible or Transient Adverse Health Consequences in the population at greatest risk using the device. There is no serious adverse health consequences expected from the delay in reporting results in the overall population using the device. There is no risk of incorrect results being reported.

ACTIONS BEING TAKEN BY THE MANUFACTURER

Microgenics Corporation is investigating the root cause of the vial-to-vial variability of the PTH analyte recovery when using the product and will take necessary actions to prevent a recurrence of this issue.

ACTIONS TO BE TAKEN BY A USER

1. Determine if you have inventory of the affected lots of **MAS® Omni•IMMUNE™ PRO Liquid Assayed Integrated Immunoassay Control** as listed in Table 1. As stated in the instructions for use, instrument values provided are specific to this lot of control only and are intended to assist the laboratory in establishing its own means and ranges.
2. If the variability of the material (PTH Analyte) exceeds your laboratory's specification, dispose of the material in accordance with local, regional, and national regulations.
3. ContactTechservice.mgc@thermofisher.com for any additional support
4. Customers using the affected product can continue to use the product as long as it meets their laboratory's specification and continue monitoring performance of PTH analyte in **MAS® Omni•IMMUNE™ PRO Liquid Assayed Integrated Immunoassay Control**
5. This Field Safety Notice needs to be passed to anyone within your organization or any organization where the potentially affected lots have been transferred.
6. Retain a copy of this letter for your laboratory records.
7. Please complete the notice response form attached to this notification within 10 days of the date of this letter and return to Thermo Fisher as instructed in the form to E-mail: MGC-FSCA@thermofisher.com.
8. If you have any additional questions regarding this notice, contact Thermo Fisher Scientific Technical Support at toll free 1-800-232-3342 (USA and Canada only) or 510-979-5000 (International), Option 2, then option 3 or by email: Techservice.mgc@thermofisher.com

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ACTIONS TO BE TAKEN BY A DISTRIBUTOR

1. Please notify your customers of this Field Safety Notice using this notice and request they return a response to your contact information.
2. For your convenience we are providing a customer response form template as a word document. Please place this letter on to your own letterhead and collect responses from your customers on that customer response form. Please note, customers should provide their response directly to your contact information.
3. Please inform users and determine if you have inventory of the affected lots of **MAS® Omni•IMMUNE™ PRO Liquid Assayed Integrated Immunoassay Control** as listed in Table 1. As stated in the instructions for use, instrument values provided are specific to this lot of control only and are intended to assist the laboratory in establishing its own means and ranges.
4. If the variability of the material (PTH Analyte) exceeds your laboratory's specification, dispose of the material in accordance with local, regional, and national regulations.
5. Contact Techservice.mgc@thermofisher.com for any additional support
6. Customers using the affected product can continue to use the product as long as it meets their laboratory's specification and continue monitoring performance of PTH analyte in **MAS® Omni•IMMUNE™ PRO Liquid Assayed Integrated Immunoassay Control**.
7. Please maintain records of all field safety notice response forms. If necessary, such as a request from a Regulatory Agency, we will request copies of these records to be provided to us.
8. Please complete the Field Safety Notice response form attached to this notice within 10 days of the date of this letter and return to Thermo Fisher as instructed in the form to E-mail: MGC- FSCA@thermofisher.com

If you have any additional questions regarding this Field Safety Notice, contact Thermo Fisher Scientific Technical Support at toll free 1-800-232-3342 (USA and Canada only) or 510-979-5000 (International), Option 2, then Option 3 or by email: Techservice.mgc@thermofisher.com

We appreciate your immediate attention to this Field Safety Notice. Please distribute this information immediately to any staff that may be impacted by this issue. We apologize for any inconvenience this may have caused and appreciate your understanding as we take action to ensure customer safety and satisfaction.

Sincerely,

Samantha Ahern

Electronically signed by:
Samantha Ahern
Reason: Approver of the GxP document
Date: Aug 18, 2026 12:48:24 PDT

Samantha Ahern, MBA
Clinical Diagnostics Division
Site Quality Head NDx, Fremont, CA

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URGENT- FIELD SAFETY NOTICE RESPONSE FORM (Distributors Only)
(FSCA 01-26-M)
Thermo Fisher Scientific MAS® Omni•IMMUNE™ PRO Liquid Assayed Integrated Immunoassay Control

☐ I confirm I have read, understood, and have taken action or determined no action is needed at our location according to the attached safety notice instructions.

☐ I am a distributor of the affected product, and I understand that this field safety notice applies to the medical device listed in Table below.

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Do you have any knowledge of adverse medical events associated with the products listed in this Field Safety Notification?

☐ Yes ☐ No

If yes, please explain and contact MGC-FSCA@thermofisher.com

PLEASE RETURN COMPLETED AND SIGNED FORM TO EMAIL WITHIN 10 DAYS UPON RECEIPT to MGC-FSCA@thermofisher.com

Name/Title:	
Date:	
Company/Institute:	
Phone:	
Email:	
Signature:	

It is important that your organization takes action as detailed in this letter and also replies without delay by using this response form. Your reply is evidence, which Thermo Fisher Scientific and Regulatory Authorities need to monitor the progress.